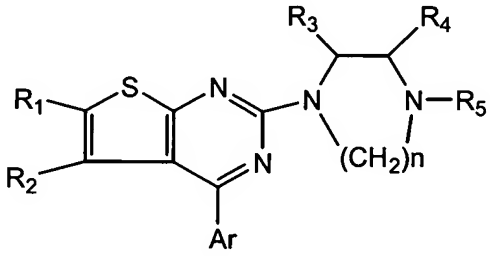
CLAIMS

What is claimed is:

1. A method of treating at least one symptom of a lower urinary tract disorder in a subject in need of treatment, wherein the symptom is selected from the group consisting of urinary frequency, urinary urgency, nocturia and enuresis, comprising administering to said subject a therapeutically effective amount of a compound of Formula I:

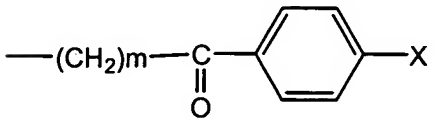


I

wherein, R_1 and R_2 independently represent hydrogen, halogen or a C_1-C_6 alkyl group; or R_1 and R_2 together with the carbon atom to which they are attached form a cycloalkylene group having 5 to 6 carbon atoms;

R_3 and R_4 independently represent hydrogen or a C_1-C_6 alkyl group;

R_5 is hydrogen, C_1-C_6 alkyl,



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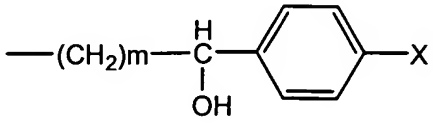


or -C(O)-NH-R_6

wherein m is an integer from about 1 to about 3, X is halogen and R_6 is a C_1-C_6 alkyl group; and

Ar is a substituted or unsubstituted phenyl, 2-thienyl or 3-thienyl group; and

n is 2 or 3; or a pharmaceutically acceptable salt thereof.

2. The method of Claim 1, wherein the lower urinary tract disorder is selected from the group consisting of overactive bladder, interstitial cystitis, prostatitis, prostadynia and benign prostatic hyperplasia.

3. The method of Claim 2, wherein the lower urinary tract disorder is overactive bladder.

4. The method of Claim 2, wherein the lower urinary tract disorder is interstitial cystitis.

5. The method of Claim 1, wherein the subject is a human.

6. The method of Claim 1, wherein for the compound of Formula I, R_1 is a C_1-C_6 alkyl group and Ar is a substituted phenyl.

7. The method of Claim 6, wherein the substituted phenyl group is substituted with a halogen.

8. The method of Claim 1, wherein for the compound of Formula I, n is 2, R_1 is a C_1-C_6 alkyl group and Ar is a substituted phenyl.

9. The method of Claim 8, wherein the substituted phenyl group is substituted with a halogen and R_1 is a methyl group.

10. The method of Claim 1, wherein for the compound of Formula I, R_1 is a C_1-C_6 alkyl group or a halogen and Ar is an unsubstituted phenyl.

11. The method of Claim 10, wherein R_2 is hydrogen or a C_1-C_6 alkyl group.

12. The method of Claim 1, wherein for the compound of Formula I, n is 2, R_1 is a C_1-C_6 alkyl group and Ar is an unsubstituted phenyl.

13. The method of Claim 12, wherein R_2 is hydrogen or a C_1-C_6 alkyl group.

14. The method of Claim 1, wherein the compound of Formula I is administered on an as-needed basis.

15. The method of Claim 14, wherein the compound of Formula I is administered prior to commencement of an activity wherein suppression of at least one symptom of overactive bladder is desired.

16. The method of Claim 14, wherein the compound of Formula I is administered from about 0 minutes to about 10 hours prior to commencement of an activity wherein suppression of at least one symptom of overactive bladder is desired.

17. The method of Claim 16, wherein the compound of Formula I is administered from about 0 minutes to about 3 hours prior to commencement of an activity wherein suppression of at least one symptom of overactive bladder is desired.

18. The method of Claim 1, wherein the compound of Formula I is administered in a controlled release formulation.

19. The method of Claim 18, wherein the compound of Formula I is administered in a delayed release formulation.

20. The method of Claim 18, wherein the compound of Formula I is administered in a pulsatile release formulation.

21. The method of Claim 18, wherein the compound of Formula I is administered in a sustained release formulation.

22. The method of Claim 1, wherein the compound of Formula I is administered orally.

23. The method of Claim 22, wherein the compound of Formula I is administered in a dosage form selected from the group consisting of: a tablet, a capsule, a caplet, a pill, a gel cap, a troche, a lozenge, a magma, a dispersion, a solution, a suspension, a syrup, a granule, a bead, a powder and a pellet.

24. The method of Claim 23, wherein the dosage form is a tablet.

25. The method of Claim 23, wherein the dosage form is a capsule.

26. The method of Claim 1, wherein the compound of Formula I is administered transmucosally.

27. The method of Claim 26, wherein the compound of Formula I is administered sublingually.

28. The method of Claim 26, wherein the compound of Formula I is administered bucally.

29. The method of Claim 26, wherein the compound of Formula I is administered transurethrally.

30. The method of Claim 26, wherein the compound of Formula I is administered rectally.

31. The method of Claim 1, wherein the compound of Formula I is administered by inhalation.

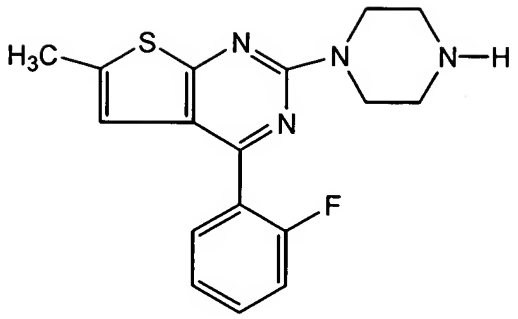
32. The method of Claim 1, wherein the compound of Formula I is administered intravesically.

33. The method of Claim 1, wherein the compound of Formula I is administered topically.

34. The method of Claim 1, wherein the compound of Formula I is administered transdermally.

35. The method of Claim 1, wherein the compound of Formula I is administered parenterally.

36. A method of treating at least one symptom of a lower urinary tract disorder in a subject in need of treatment, wherein the symptom is selected from the group consisting of urinary frequency, urinary urgency, nocturia and enuresis, comprising administering to said subject a therapeutically effective amount of a compound represented by Formula II:



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or a pharmaceutically acceptable salt thereof.

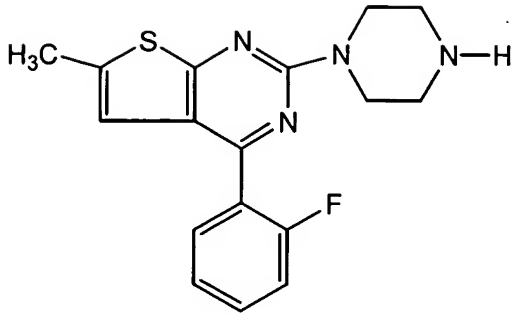
37. The method of Claim 36, wherein the lower urinary tract disorder is selected from the group consisting of overactive bladder, interstitial cystitis, prostatitis, prostadynia and benign prostatic hyperplasia.

38. The method of Claim 37, wherein the lower urinary tract disorder is overactive bladder.

39. The method of Claim 37, wherein the lower urinary tract disorder is interstitial cystitis.

40. The method of Claim 36, wherein the subject is a human.

41. A method of treating at least one symptom of overactive bladder in a subject in need of treatment, wherein the symptom is selected from the group consisting of urinary frequency, urinary urgency, nocturia and enuresis, comprising administering to said subject a therapeutically effective amount of a compound represented by Formula II:

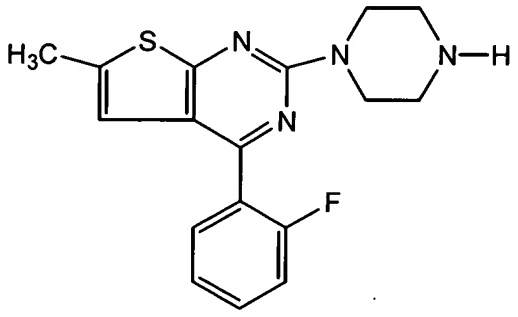


II

or a pharmaceutically acceptable salt thereof.

42. The method of Claim 41, wherein the subject is a human.

43. A method of treating at least one symptom of interstitial cystitis in a subject in need of treatment, wherein the symptom is selected from the group consisting of urinary frequency, urinary urgency, nocturia and enuresis, comprising administering to said subject a therapeutically effective amount of a compound represented by Formula II:



II

or a pharmaceutically acceptable salt thereof.

44. The method of Claim 43, wherein the subject is a human.

45. A method of treating at least one symptom of a lower urinary tract disorder in a subject in need of treatment, wherein the symptom is selected from the group consisting of urinary frequency, urinary urgency, nocturia and enuresis, comprising administering to said subject:

a) a first amount of a 5-HT_3 receptor antagonist; and

b) a second amount of a noradrenaline reuptake inhibitor

wherein the first and second amounts together comprise a therapeutically effective amount.

46. The method of Claim 45, wherein the lower urinary tract disorder is selected from the group consisting of overactive bladder, interstitial cystitis, prostatitis, prostadynia and benign prostatic hyperplasia.

47. The method of Claim 46, wherein the lower urinary tract disorder is overactive bladder.

48. The method of Claim 46, wherein the lower urinary tract disorder is interstitial cystitis.

49. The method of Claim 45, wherein the subject is a human.

50. The method of Claim 45, wherein the 5-HT_3 receptor antagonist is selected from the group consisting of indisetron, YM-114 ((R)-2,3-dihydro-1-[(4,5,6,7-tetrahydro-1H-benzimidazol-5-yl-)carbonyl]-1H-indole), granisetron, talipexole, azasetron, bemesetron, tropisetron, ramosetron, ondansetron, palonosetron, lerisetron, alosetron, N-3389, zacopride, cilansetron, E-3620 ([3(S)-endo]-4-amino-5-chloro-N-(8-methyl-8-azabicyclo[3.2.1-]oct-3-yl-2[(1-methyl-2-

butynyl)oxy]benzamide), lintopride, KAE-393, itasetron, zatosetron, dolasetron, (±)-zacopride, (±)-renzapride, (-)-YM-060, DAU-6236, BIMU-8 and GK-128 ([2-[2-methylimidazol-1-yl)methyl]-benzo[*f*]thiochromen-1-one monohydrochloride hemihydrate]).

51. The method of Claim 50, wherein the 5-HT_3 receptor antagonist is selected from the group consisiting of indisetron, granisetron, azasetron, bemesetron, tropisetron, ramosetron, ondansetron, palonosetron, lerisetron, alosetron, cilansetron, itasetron, zatosetron, and dolasetron.

52. The method of Claim 45, wherein the noradrenaline reuptake inhibitor is selected from the group consisting of venlafaxine, duloxetine, buproprion, milnacipran, reboxetine, lefepramine, desipramine, nortriptyline, tomoxetine, maprotiline, oxaprotiline, levoprotiline, viloxazine and atomoxetine.

53. The method of Claim 52, wherein the noradrenaline reuptake inhibitor is selected from the group consisting of reboxetine, lefepramine, desipramine, nortriptyline, tomoxetine, maprotiline, oxaprotiline, levoprotiline, viloxazine and atomoxetine.

54. A method of treating at least one symptom of a lower urinary tract disorder in a subject in need of treatment, wherein the symptom is selected from the group consisting of urinary frequency, urinary urgency, nocturia and enuresis, comprising administering to said subject:

a) a therapeutically effective amount of a 5-HT_3 receptor antagonist; and

b) a therapeutically effective amount of a noradrenaline reuptake inhibitor.

55. The method of Claim 54, wherein the lower urinary tract disorder is selected from the group consisting of overactive bladder, interstitial cystitis, prostatitis, prostadynia and benign prostatic hyperplasia.

56. The method of Claim 55, wherein the lower urinary tract disorder is overactive bladder.

57. The method of Claim 55, wherein the lower urinary tract disorder is interstitial cystitis.

58. The method of Claim 54, wherein the subject is a human.

59. The method of Claim 54, wherein the 5-HT_3 receptor antagonist is selected from the group consisting of indisetron, YM-114 ((R)-2,3-dihydro-1-[(4,5,6,7-tetrahydro-1H-benzimidazol-5-yl-)carbonyl]-1H-indole), granisetron, talipexole, azasetron, bemesetron, tropisetron, ramosetron, ondansetron, palonosetron, lerisetron, alosetron, N-3389, zacopride, cilansetron, E-3620 ([3(S)-endo]-4-amino-5-chloro-N-(8-methyl-8-azabicyclo[3.2.1-]oct-3-yl-2[(1-methyl-2-butynyl)oxy]benzamide), lintopride, KAE-393, itasetron, zatosetron, dolasetron, (±)-zacopride, (±)-renzapride, (-)-YM-060, DAU-6236, BIMU-8 and GK-128 ([2-[2-methylimidazol-1-yl)methyl]-benzo[*f*]thiochromen-1-one monohydrochloride hemihydrate]).

60. The method of Claim 59, wherein the 5-HT_3 receptor antagonist is selected from the group consisiting of indisetron, granisetron, azasetron, bemesetron, tropisetron, ramosetron, ondansetron, palonosetron, lerisetron, alosetron, cilansetron, itasetron, zatosetron, and dolasetron.

61. The method of Claim 54, wherein the noradrenaline reuptake inhibitor is selected from the group consisting of venlafaxine, duloxetine, buproprion, milnacipran, reboxetine, lefepramine, desipramine, nortriptyline, tomoxetine, maprotiline, oxaprotiline, levoprotiline, viloxazine and atomoxetine.

62. The method of Claim 61, wherein the noradrenaline reuptake inhibitor is selected from the group consisting of reboxetine, lefepramine, desipramine, nortriptyline, tomoxetine, maprotiline, oxaprotiline, levoprotiline, viloxazine and atomoxetine.

63. A method for processing a claim under a health insurance policy submitted by a claimant seeking reimbursement for costs associated with treatment of at least one symptom of a lower urinary tract disorder wherein, said treatment comprises coadministering to a subject a first amount of a 5-HT_3 receptor antagonist and a second amount of a noradrenaline reuptake inhibitor, wherein the first and second amounts together comprise a therapeutically effective amount comprising:

a) reviewing said claim;

b) determining whether said treatment is reimbursable under said insurance policy; and

c) processing said claim to provide partial or complete reimbursement of said costs.

64. The method of Claim 63, wherein the lower urinary tract disorder is selected from the group consisting of overactive bladder, interstitial cystitis, prostatitis, prostadynia and benign prostatic hyperplasia.

65. The method of Claim 64, wherein the lower urinary tract disorder is overactive bladder.

66. The method of Claim 64, wherein the lower urinary tract disorder is interstitial cystitis.

67. A method for processing a claim under a health insurance policy submitted by a claimant seeking reimbursement for costs associated with treatment of at least one symptom of a lower urinary tract disorder wherein, said treatment comprises coadministering to a subject a therapeutically effective amount of a 5-HT_3 receptor antagonist and a therapeutically effective amount of a noradrenaline reuptake inhibitor comprising:

a) reviewing said claim;

b) determining whether said treatment is reimbursable under said insurance policy; and

c) processing said claim to provide partial or complete reimbursement of said costs.

68. The method of Claim 67, wherein the lower urinary tract disorder is selected from the group consisting of overactive bladder, interstitial cystitis, prostatitis, prostadynia and benign prostatic hyperplasia.

69. The method of Claim 68, wherein the lower urinary tract disorder is overactive bladder.

70. The method of Claim 68, wherein the lower urinary tract disorder is interstitial cystitis.